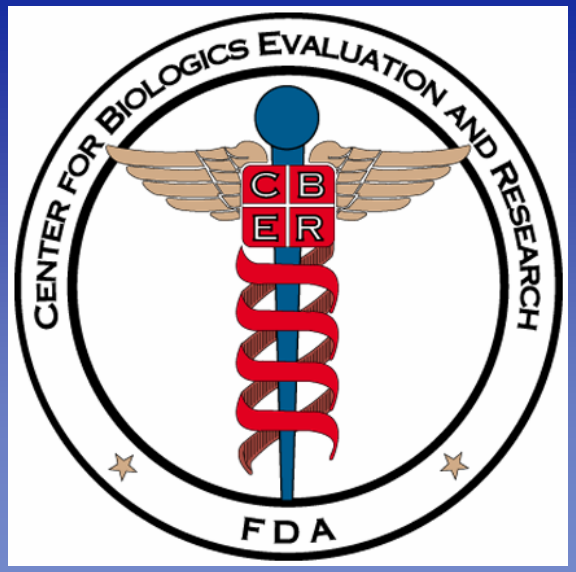

Introduction to Regulation

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Contents

- History of FDA (short version)
- FDA/CBER Structure
- Regulatory Framework
  - Laws
  - Regulations
  - Guidance
- Practical Advice

Short Legislative History

- **Biologics Control Act (1902) (*Biologics*)**
  - **Began federal regulation of *biologics***
- **Food and Drugs Act (1906) (*Food & Drugs*)**
  - **Began federal regulation of *drugs***
  - **FD&C Act amended (1938) (*Food, Drugs, Devices, Cosmetics, Safety)***
- **PHS Act (1944) (*Regulation of Biologics and Control of Communicable Diseases)***

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Short Legislative History

- **FD&C amended (1962)("Kefauver Amendments") (*Efficacy)***
- **FD&C (1976) Medical Device Amendments**
  - **Established medical device regulations (previously devices regulated as drugs!)**
  - **FD&C amended (1990) Safe Medical Devices Act and (1992) Medical Device Amendments that fine tuned device law**

Short Legislative History

- **PDUFA (1992) Prescription Drug User Fee Act (PDUFA I)**
  - **Allows fees to be charged for review**
  - **Reviews must be completed "on-time"**
    - **Timelines found in letter from HHS Secretary to Congress**
      - **Text of the June 4, 2002, letter transmitting the PDUFA III performance goals and procedures (10/2003) http://www.fda.gov/cder/pdufa/default.htm**
  - **Renewed every 5 years with some changes**

Short Legislative History

- **FD&C (1997) Modernization Act (PDUFA II)**
  - **Renewed PDUFA with some changes, e.g., structures meetings with industry plus others**
- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PDUFA III)**
  - **Renewed PDFUA with some changes, e.g., Continuous Marketing Application Pilots plus others**

Department of Health and Human Services

- **Office of the Secretary**
- **Administration for Children and Families**
- **Administration on Aging**
- **Agency for Healthcare Research and Quality**
- **Agency for Toxic Substances and Disease Registry**
- **Program Support Center**
- **Substance Abuse and Mental Health Services Administration**
- **Centers for Disease Control and Prevention**
- **Centers for Medicare and Medicaid Services**
- Food and Drug Administration
- **Health Resources and Services Administration**
- **Indian Health Service**
- **National Institutes of Health**

Food and Drug Administration

- **Office of the Commissioner**
- **Center for Biologics Evaluation and Research**
- **Center for Drug Evaluation and Research**
- **Center for Devices and Radiologic Health**
- **Center for Veterinary Medicine**
- **Center for Food Safety and Applied Nutrition**
- **National Center for Toxicological Research**
- **Office of Regulatory Affairs**

CBER Structure

- **Office of Communication, Training and Manufacturers Assistance**
- **Office of Management**
- **Office of Blood Research and Review**
- **Office of Cellular, Tissues and Gene Therapy**
- **Office of Vaccines Research and Review**
- **Office of Biostatistics and Epidemiology**
- **Office of Compliance and Biologic Quality**

Vision for CBER

Innovative Technology
Advancing Public Health

Protect and improve public and individual health in the US, and if possible, globally

Facilitate development, approval and access to safe and effective products

Strengthen CBER as preeminent regulatory Agency for biologics

LEGAL FRAMEWORK

- **STATUTES**
- **REGULATIONS**
- **GUIDANCE**

STATUTES

- **PUBLIC HEALTH SERVICE ACT**
  - **licensing provisions**
  - **prevent communicable disease**
- **Federal Food, Drug and Cosmetic Act**
  - **Investigational New Drug Applications**
- **Other Statutes**
  - **e.g. Administrative Procedure Act**
  - **Federal Advisory Committee Act**

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Regulations

- Created under statutory authorities (PHS Act and FDC Act)
- Designed to implement, interpret, or prescribe law or policy
- Establishes requirements
- Has binding effect on both you and the Agency

Regulations of Interest

- **Investigational New Drug application: 21CFR 312**
- **Informed Consent 21 CFR 50**
- **Institutional Review Boards 21 CFR 54**
- **Biologics 21 CFR 600**
- **Tissues 21 CFR 1270/1271**
- **Recalls 21 CFR 7**

What is a Guidance Document?
(21 CFR 10.115(b))

- A document that describes FDA's interpretation of or policy on a regulatory issue; or
- Relates to
  - The design, production, labeling, promotion, manufacturing, and testing of regulated products;
  - The processing, content, and evaluation or approval of submissions; and
  - Inspection and enforcement policies.
- FDA's current thinking on an issue

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Guidance Documents

- Guidance documents are NOT regulations
- Guidance documents CANNOT be enforced
- You may chose an alternative approach that complies with laws and regulations
- FDA can deviate from guidance but may do so only with supervisory approval

Practical Advice

- **Make use of your resources!**
  - Regulatory Compliance and Human Subjects Protection Branch
- **CBER is Here to Help You**
  - On-line
  - On the telephone

FDA U.S. Food and Drug Administration

Department of Health and Human Services

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What's New at CBER

Product Approvals

- Botulism Immune Globulin Intravenous (Human), (BabyBIG)

Recalls

- Recall of Immune Globulin Intravenous (Human) 10% Solvent/Detergent Treated, Gamimune

Guidances

Safety Information

Consumer Information

Transfer of Therapeutic Products to CDER

Countering Bioterrorism
Information available on Anthrax; FDA and CDC's Bioterrorism information; FAQ's

Vaccine Adverse Event Reporting System (VAERS)

Monkeypox Virus Infections and Blood & Plasma Donors

Smallpox

Severe Acute Respiratory Syndrome (SARS)

Postmarketing Study Commitments

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Impact of Severe Weather Conditions on Biological Products

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We're Here to Help You!

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  - **Consumers, health care professionals: octma@cber.fda.gov**
- **Phone: 800-835-4709/301-827-1800**
- **Listserv: http://www.fda.gov/cber/pubinfo/elists.htm**

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